REMARKS

Entry of the foregoing and further and favorable reconsideration of the subject application, in light of the following remarks, is respectfully requested. By the foregoing amendment, claim 1 has been amended to recite that the antibodies bind specifically to the ubiquitination-regulating domain, or a fragment thereof. Support for this amendment to claim 1 may be found, at the very least, on page 16, line 11, to page 18, line 22, of the specification as filed. No new matter enters by this amendment.

Rejection of Claims 1, 4-6 and 43 Under 35 U.S.C. § 112, First Paragraph

Claims 1, 4-6 and 43 have been rejected, under 35 U.S.C. § 112, first paragraph, for purportedly failing to convey to one of skill in the art that the inventors, at the time the application was filed, has possession of the claimed genus of polypeptides, comprising ubiquitination-regulating domains or functional fragments thereof. For at least all of the reasons set forth below, withdrawal of this rejection is believed to be in order.

The Examiner, while conceding that the specification does provide written description support for the ubiquitination-regulating domain of TSG101 and deletion fragments of human TSG101, purports that the specification does not appear to provide written description support for any/or all polypeptides comprising functional fragments of an ubiquitination-regulating domain comprising the amino acid sequence of SEQ ID NO:1. While Applicants agree with the Examiner that the specification does provide written description support for the ubiquitination-regulating domain of TSG101 and deletion fragments of human TSG101, Applicants respectfully disagree with the Examiner's assertion that there is not adequate written description support for any/or all polypeptides comprising functional fragments of an ubiquitination-regulating domain comprising the amino acid sequence of SEQ ID NO:1.

The written description requirement for a claimed genus may be satisfied by describing a representative number of species by actual reduction to practice or by disclosure of relevant identifying characteristics, such as functional characteristics coupled with a known or disclosed correlation between function and structure. *See*

MPEP § 2163 IIA3(a)(ii) and *Regents of University of California v. Eli Lilly & Co.*, 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). Not only does the specification provide reduction to practice of a representative number of species (see, for example, the fragments listed on page 24, last paragraph, of the specification), it also discloses functional characteristics shared by all of the species and a correlation between function and structure.

As noted on page 12, lines 3-4, of the specification as filed, "a functional fragment of an ubiquitination-conjugase-like Ubc domain refers to any fragment of the Ubc domain that regulates ubiquitination." Thus, the functional characteristic shared by all of the species encompassed by the claimed genus "...ubiquitination-regulating domain, or a functional fragment thereof..." is the ability to regulate ubiquitination. On page 26 of the specification as filed the Applicants disclose a method by which one can determine which fragments of a ubiquitination-regulating domain regulate ubiquitination. Thus, the specification teaches one of skill in the art how to identify functional fragments of a ubiquitination-regulating domain. Furthermore, Applicants have identified a correlation between function and structure. As shown in Figure 3(a) of the specification as filed, amino-acids 1-250 of human TSG101 protein (the ubiquitination-regulating domain), or fragments thereof, were identified by the Applicants as having the function of regulating ubiquitination.

Therefore, the Applicants have not only identified a representative number of species encompassed by the claimed invention, they have also identified functional characteristics shared by all of the species encompassed by the claimed invention as well as a correlation between the function (regulating ubiquitination) and structure (amino acids 1-250 of SEQ ID NO:1, or fragments thereof). It is thus clear that the written description requirement has been met.

In light of the above, withdrawal of this rejection under 35 U.S.C. § 112, first paragraph, is respectfully requested.

Rejections of Claims 1, 4-6 and 43 Under 35 U.S.C. § 102(b)

Claims 1, 4 and 6 have been rejected under 35 U.S.C. § 102(b) for purportedly being anticipated by Li *et al.* (U.S. Patent No. 5,891,668). Claims 1, 4-6 and 43 have

been rejected under 35 U.S.C. § 102(b) for purportedly being anticipated by Brie *et al.* (U.S. Patent No. 5,892,016). For at least all of the reasons set forth below, withdrawal of these rejections is believed to be in order.

In order to expedite prosecution of the above-identified application, Applicants have amended claim 1 to recite that the antibodies bind to the ubiquitination-regulating domain, or a functional fragment thereof. It is the ability of the claimed antibodies to bind to the ubiquitination-regulating domain, or a functional fragment thereof, that provides the patentable difference between the claimed antibodies and those purportedly disclosed in the prior art. As noted previously, Li *et al.* and Brie *et al.* each describe a genus of antibodies that bind to the full length TSG101, while the present invention discloses a species of that genus (*i.e.*, antibodies that bind specifically to the ubiquitination-regulating domain of human TSG101). A genus does not always anticipate a claim to a species within the genus, if the species is not specifically taught (*See* MPEP, 2131.02). Since neither Li *et al.* nor Brie *et al.* teach or suggest the existence of a ubiquitination-regulating domain within the TSG101 protein, neither of these references teach or suggest an antibody that binds to this region. Accordingly, the species claimed in the present invention is not anticipated by the genus described in Li *et al.* and Brie *et al.*

Furthermore, binding to the ubiquitination-regulating domain is not an inherent characteristic of the antibodies of Li *et al.* or Brie *et al.* Inherency may not be established by probabilities or possibilities. The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient. *In re Rijckaert*, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993) and MPEP § 2112 IV. "[T]he examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original). In the present case, due to protein folding, etc., antibodies developed to the full length TSG101 may not necessarily bind to the ubiquitination-regulating domain.

In light of the above, withdrawal of these rejections under 35 U.S.C. § 102(b) are respectfully requested.

CONCLUSION

In view of the above amendments and remarks, Applicant respectfully requests a Notice of Allowance. If the Examiner believes a telephone conference would advance the prosecution of this application, the Examiner is invited to telephone the undersigned at the below-listed telephone number.

Respectfully submitted,

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October 31, 2005
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